NON-FORMULARY PHARMACY PRIOR AUTHORIZATION
Clinical Guideline-Injectable Osteoporosis Therapy
Forteo® (teriparatide); Boniva® (ibandronate sodium); Reclast® (zoledronic acid); Prolia (denosumab)]

Indications:
Reclast (zoledronic acid): zoledronic acid is a bisphosphonate
• Treatment of osteoporosis
  o In postmenopausal women
  o Secondary fracture prophylaxis in high-risk patients
• Increase bone mass in men with osteoporosis
• Treatment of Paget’s disease of bone in men and women
• Prevention and treatment of glucocorticoid-induced osteoporosis

Boniva (ibandronate sodium): ibandronate sodium is a bisphosphonate
• Treatment of osteoporosis in postmenopausal women
• Treatment of corticosteroid-induced osteoporosis*
• Treatment of Paget’s disease*
• Treatment of osteolytic metastases in patients with prostate cancer*
• Treatment of hypercalcemia of malignancy*

Forteo (teriparatide): teriparatide is recombinant parathyroid hormone (PTH)
• Postmenopausal women: For the treatment of postmenopausal women with osteoporosis who are at high risk for fracture.
• Men: To increase bone mass in men with primary of hypogonadal osteoporosis who are at high risk for fracture.
• Corticosteroid-induced osteoporosis*
• Hypoparathyroidism*

Prolia (denosumab)
• Treatment and Prevention of osteoporosis in postmenopausal women
• Bone loss in women taking an aromatase inhibitor for breast CA
• Bone loss in men receiving androgen deprivation therapy for prostate CA

*Off-label use - based on peer-reviewed clinical studies
Authorization Guidelines:
For Patients who meet all of the following:

**Boniva/Prolia**
- For the treatment of osteoporosis in postmenopausal women who meet one of the following:
  - Intolerant to or failure after compliant trial of formulary oral bisphosphonate therapy:
    - **Medical documentation supporting failure**
    - **Decrease in T-score in comparison with baseline T-score from DEXA scan**
    - **New fracture**
  - Receiving concomitant elemental calcium supplementation of 1200-1500 mg and 400 - 1000 IU of vitamin D supplementation per day
  - History of osteoporotic fracture or at high risk for fracture
    - For postmenopausal women who meet one of the following criteria:
      - T score= less than -2.5
      - T score between -2.0 and -2.5 who also have at least one risk factors for fracture: thinness [body weight less than 127 pounds (57.7kg) or low BMI [less than 21kg/m²]]
      - History of fragility fracture since menopause, or history of hip fracture in a patient
      - Age ≥ 65 years
      - Family history of osteoporosis (1st degree relative)
      - Type 1 diabetes
      - Chronic liver disease
      - Premature menopause (< 45 years)

**Reclast**
- For the treatment and prevention of osteoporosis in men and women who meet one of the following:
  - Intolerant to or failure after compliant trial of formulary oral bisphosphonate therapy:
    - **Medical documentation supporting failure**
    - **Decrease in T-score in comparison with baseline T-score from DEXA scan**
    - **New fracture**
  - Receiving concomitant elemental calcium supplementation of 1200-1500 mg and 400 - 1000 IU of vitamin D supplementation per day
  - History of osteoporotic fracture or at high risk for fracture
    - For postmenopausal women or men who meet one of the following criteria:
      - T score= less than -2.5
      - T score between -2.0 and -2.5 who also have at least one risk factors for fracture: thinness [body weight less than 127 pounds (57.7kg) or low BMI [less than 21kg/m²]]
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Clinical Practice Guideline

- History of fragility fracture since menopause, or history of hip fracture in a PARENT
- Age ≥ 65 years
- Family history of osteoporosis (1st degree relative)
- Type 1 diabetes
- Chronic liver disease
- Premature menopause (< 45 years)

For men: correction of hypogonadism with testosterone with a repeat T-score after three months of normal free testosterone levels and bisphosphonate therapy. (Exclusion: history of prostatic cancer)

- **Prevention of corticosteroid-induced osteoporosis:**
  - Treatment with greater ≥ 7.5 mg/day of oral prednisone (or equivalent) for a planned duration of at least 12 months
  - Baseline T-score
  - Receiving concomitant elemental calcium supplementation of 1200-1500 mg and 400 - 1000 IU of vitamin D supplementation per day
  - Trial and failure/ intolerance to a compliant (at least 6 months) regimen of formulary medications used for the prevention of osteoporosis (Evista, Miacalcin (for vertebral fracture), alendronate, Fortical nasal spray)

**Boniva/Reclast**

- **Treatment of Corticosteroid-induced osteoporosis:**
  - Treatment with greater ≥ 7.5 mg/day of oral prednisone (or equivalent) for a duration of at least 12 months
  - Baseline T-score of < -1, with DEXA scan,
  - Receiving concomitant elemental calcium supplementation of 1200-1500 mg and 400 - 1000 IU of vitamin D supplementation per day
  - Trial and failure/ intolerance to a compliant (at least 6 months) regimen of formulary medications used to treat osteoporosis (Evista, Miacalcin (for vertebral fracture), alendronate, Fortical nasal spray)

**Boniva/Reclast**

- For the treatment of Paget’s disease of bone in men and women who meet all of the following criteria:
  - Moderate to severe Paget’s disease of bone
  - Diagnosis confirmed by medical records with a serum alkaline phosphatase level at least 2X ULN of age-specific normal range
  - Trial and failure/intolerance to a compliant (at least 2 months) regimen of formulary medications used to treat Paget’s (calcitonin, alendronate,)
Forteo

- **Osteoporosis:**
  - T score less than or equal to -3 with a previous vertebral fracture
  - Documented failure of oral bisphosphonate despite compliance *(including new fracture or reduction in BMD per recent DEXA scan)*.
  - Trial and failure to a compliant (at least 6 months) regimen or Intolerance of formulary medications used to treat osteoporosis [alendronate, Evista, Miacalcin (for vertebral fracture), Fortical nasal spray]
  - Trial and failure or Intolerance to a compliant (at least 12 months) regimen of Reclast

- **Treatment of Corticosteroid-induced osteoporosis:**
  - T score less than or equal to -1
  - Documented failure of oral bisphosphonate despite compliance *(including new fracture or reduction in BMD per recent DEXA scan)*.
  - Trial and failure to a compliant (at least 6 months) regimen or Intolerance of formulary medications used to treat osteoporosis [alendronate, Evista, Miacalcin (for vertebral fracture), Fortical nasal spray]
  - Trial and failure or Intolerance to a compliant (at least 12 months) regimen of Reclast

- **Treatment of hypoparathyroidism:**
  - Trial and failure/intolerance to a compliant (at least 2 months) regimen of formulary medications used to treat hypoparathyroidism (Calcijex/ Rocaltrol, ergocalciferol)

Prolia

- **For the treatment of bone loss in men with osteoporosis at high risk for fracture or at high risk and receiving androgen deprivation therapy for nonmetastatic prostate cancer who meet one of the following:**
  - Adult > 18 years of age
  - No pre-existing hypocalcemia

**Initial Approval:**

- Osteoporosis
  - 1 year
  - Baseline T-score from DEXA scan
- Progress notes (documented intolerance/failure of approved formulary medications)

**Hypoparathyroidism**
- 3 months
- Parathyroid hormone level (PTH)--within last 30 days
- Progress notes (documented intolerance/failure of approved formulary medications)

**Paget’s disease (excludes Forteo)**
- 1 year
- Progress notes (documented intolerance/failure of approved formulary medications)
- Serum alkaline phosphatase level – within last 30 days

**Renewal:**
- 1 year
- Parathyroid (PTH) level (hypoparathyroidism)
- Testosterone level (men with osteoporosis)
- Increases in serum alkaline phosphatase level (relapse) and/or failure to achieve normalization of serum alkaline phosphatase (Paget’s disease)
- Progress notes
References: